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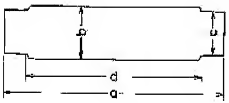
(54) BALLOON FOR BALLOON CATHETER, AND ITS MANUFACTURE

(57)Abstract:
PROBLEM TO BE SOLVED: To provide a balloon for a balloon catheter, and a manufacturing method therefor in which a balloon can be expanded without becoming largely eccentric and it can be set in a vessel for a long period without generating a thrombus, and which can be favorably used for inspection or treatment using a heart catheter.
SOLUTION: In a balloon installed at a farther end part of a balloon catheter, a ratio d/a of a length (d) of an expanded part of the balloon to a length (a) of the whole body of the balloon is 0.4-0.95, and a ratio b/c of an outer diameter (b) of the expanded part of the balloon to an outer diameter (c) of a bound part of the balloon is 1.03-1.3. The manufacturing method comprises pressing a tube comprising elastomer of elongation of 500% or more and permanent elongation of 3-30% at both end parts as balloon binding parts to be fixed, and closing one end of the tube and injecting gas or liquid from the other end to expand an outer diameter of the tube by four times or more to be molded.



DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention]This invention relates to a balloon for balloon catheters, and a manufacturing method for the same. This invention expands in more detail, without a balloon carrying out eccentricity greatly, Even if it detains in a blood vessel over a long period of time, a possibility of generating a thrombus is related with a balloon for the balloon catheters which can be used conveniently [it is few and] for an inspection, a therapy, etc. especially using a cardiac catheter, and a manufacturing method for the same.

[0002]

[Description of the Prior Art]A catheter is inserted in the heart, a main artery, the pulmonary artery, a coronary artery, etc. from a peripheral vessel for the purpose of the confirmed diagnosis of the abnormalities of the mind of the patient who has a heart disease, and grasp of severity, and internal pressure measurement, oxygen content measurement, cardiac angiography, a thermodilution method, an indicator dilution method, an electrophysiology inspection, a myocardial biopsy, etc. are performed. The balloon catheter which has a balloon in a distal end had few risks of damaging the heart, and since it could put on the blood flow and advanced to a right ventricle and the pulmonary artery comparatively easily from the right atrium, it came to be used widely. On clinical, circulatory system balloon catheters, such as a thermostat dilution catheter and temporary pacing catheter, are inserted from a femoral region etc., and detain the distal end in a right atrium, a right ventricle, and also a pulmonary artery tee from vena cava. As for the balloon catheter, the distal end is generally equipped with the small balloon.

By making it expand, this balloon puts on the flow of a blood flow, and is used for the purpose, such as carrying a distal end to a target part, or measuring blood pressure by blockading a blood vessel by a balloon.

The conventional balloon catheter provides the balloon applied part whose outer diameter is smaller than the main part of a catheter tube in the distal end of a catheter tube, A tube shape balloon is inserted in a balloon applied part, and it is manufactured by pasting up the both ends of a balloon on a balloon applied part using adhesives etc. Drawing 5 (a) is a side view of the distal end of the conventional balloon catheter. The tube shape balloon 4 is inserted in the balloon applied part 3 which made the outer diameter small and was provided from the catheter tube near the distal end 2 of the catheter tube 1, and the both ends of the balloon are being fixed to the balloon applied part by adhesives in the jointing 5. Adhesion of a balloon is performed by returning the end of a balloon, after having turned over the end of the balloon usually inserted in the balloon applied part and carrying out adhesives with **. Adhesives do not adhere to uniform width in the both ends of a balloon, but according to such a method, as shown in drawing 5 (a), it is easy to produce a portion with wide adhesion width of adhesives, and a narrow portion.Drawing 5 (b) is a side view showing the state where the balloon of the balloon catheter of drawing 5 (a) was expanded. If the adhesion width of adhesives has extensive ** like

drawing 5 (a), in a portion with wide adhesion width of adhesives, the width of the expansion portion of a balloon will become narrow, and the width of the expansion portion of a balloon will become large in a portion with narrow adhesion width of adhesives. If the balloon fixed to the balloon applied part in such the state is expanded, as shown in drawing 5 (b), In the place where the width of an expansion portion is narrow, a balloon expands small, and in the place where the width of an expansion portion is wide, if a balloon expands greatly and the balloon which expanded is observed from a transverse plane, the state whose position of the center of the balloon which looks circular, and the center of a catheter tube does not correspond, and what is called eccentricity will produce it. If the expanding state of a balloon has eccentricity, when measuring a cardiac output with a thermodilution method using a balloon catheter, it becomes difficult for the flow of the chilled water poured in from a proximal hole to become uneven, and to perform exact measurement. If the expanding state of a balloon has eccentricity, when performing pressure measuring using a balloon catheter, it becomes difficult for the blockade of a blood vessel to become imperfect and to perform exact measurement. When a balloon carries out eccentricity and expanded, and the pressure in a balloon is extracted and it is made to contract, A wrinkle and sag are produced without the portion which the expansion magnification of the balloon had returning thoroughly, and when a balloon is shrunk and it detains over a long period of time in a blood vessel, the portion of a wrinkle has a problem of being easy to generate a thrombus. For this reason, it expands without a balloon carrying out eccentricity, measurement of a cardiac output or ** can be performed correctly, and development of the balloon for balloon catheters with few possibilities of generating a thrombus on a balloon is called for.

[0003]

[Problem(s) to be Solved by the Invention]A possibility of generating a thrombus even if this invention expands without a balloon carrying out eccentricity greatly and it detains in a blood vessel over a long period of time, [little] It is made for the purpose of providing a balloon for the balloon catheters which can be used conveniently for an inspection, a therapy, etc. using a cardiac catheter, and a manufacturing method for the same.

[0004]

[Means for Solving the Problem]As a result of repeating research wholeheartedly that this invention persons should solve the above-mentioned technical problem, a balloon in which an outer diameter of an inflating part of a balloon is slightly formed greatly compared with an outer diameter of jointing of a balloon, By finding out that it is [which has carrying out / little / eccentricity at the time of expansion] rare to produce a thrombus even if it detains in a blood vessel, and expanding beforehand an elastomer tube which has a still more specific permanent set, It finds out that a balloon of such shape can be manufactured easily, and came to complete this invention based on these knowledge.Namely, this invention is a balloon with which a distal end of (1) balloon catheter is equipped, a ratio of length d of an inflating part of a balloon to length a of the whole balloon -- d/a being 0.4-0.95 and, and a ratio of the outer diameter b of an inflating part of a balloon to the outer diameter c of jointing of a balloon -- a balloon for balloon catheters, wherein b/c is 1.03-1.3. And press down a both-ends portion used as jointing of a balloon of a tube which consists of an elastomer whose (2) elongation is not less than 500%, and whose permanent set is 3 to 30% from a peripheral part, and it fixes, One end

of a tube is blockaded and a manufacturing method of a balloon for balloon catheters given in ** (1) paragraph fabricating by pouring in a gas or a fluid and expanding an outer diameter of a tube from the other end to 4 or more times is provided.
[0005]
[Embodiment of the Invention]The balloon for the balloon catheters of this invention consists of an inflating part of the center of a balloon, and jointing of both ends, and its outer diameter of an inflating part is more slightly [than the outer diameter of jointing] large. Drawing 1 (a) is a side view of the distal end of one mode equipped with the balloon of this invention of a balloon catheter. The distal end 2 of the catheter tube 1 is processed into curved surface shape, and the balloon applied part 3 provided near the distal end is equipped with the balloon 4. When inserting the balloon of this invention in a balloon applied part, a balloon applied part is touched only in the jointing 5 of a balloon, and the opening 7 exists between the inflating part 6 of a balloon, and a balloon applied part. Therefore, when making adhesives jointing of a balloon with ** and pasting up a balloon, adhesives are pasted up in the circumference surface of equal width, and the end of the adhesion portion of adhesives does not shift irregularly like the conventional balloon shown in drawing 5 (a). Although there is no restriction in particular in the method of making adhesives jointing of a balloon with **, jointing of a balloon has been rolled up after usually inserting a balloon in a balloon applied part, Adhesives can be made with ** the exposed balloon applied part, and adhesion without the flash of adhesives can be performed by returning a balloon. Although there is no restriction in particular in the adhesives to be used, since a high pressure is not usually applied to a balloon, bonding time can use the short good cyanoacrylate adhesive of workability, etc. conveniently. Drawing 1 (b) is a sectional view of the distal end of the balloon catheter equipped with the balloon of drawing 1 (a). A catheter tube can be equipped with lumens according to the purpose of use, such as a lumen for pressure surveies, a lumen for chemical feeding, and a lumen for electrodes besides the lumen for the gases for blowing up a balloon. In this sectional view, the lumen 8 for the gases for blowing up a balloon and the lumen 9 for pressure surveies are shown, the lumen for gases has puncturing in the position equivalent to the inflating part of a balloon, and the lumen for pressure surveies has puncturing in a distal end. Drawing 1 (c) is a side view showing the state where the balloon of the balloon catheter of drawing 1 (a) was expanded. Since the inflating part swelled easily since the swelling was beforehand given to the inflating part of the balloon, and the balloon has pasted up the balloon of this invention on the balloon applied part only in jointing correctly, When pressing a gas fit in a balloon and expanding a balloon, a balloon expands symmetrically to the medial axis of a catheter tube, without carrying out eccentricity.
[0006]Drawing 2 is a size explanatory view of the balloon of this invention. The balloon of this invention consists of a central inflating part and jointing of both ends, and its outer diameter of an inflating part is slightly large compared with the outer diameter of jointing. When the balloon of this invention sets the length of the inflating part of a and a balloon to d for the length of the whole balloon, a ratio -- d/a -- 0.4 to 0.95, and the time of being 0.6-0.8 more preferably and setting the outer diameter of jointing of b and a balloon to c for the outer diameter of the inflating part of a balloon -- a ratio -- b/c -- 1.03-1.3 -- it is 1.1-1.2 more preferably. the ratio of length d of the inflating part of a balloon to length a of the whole balloon -- there is a possibility that the inflating part of a balloon may

become it small that d/a is less than 0.4, and it may become difficult to expand a balloon greatly. the ratio of length d of the inflating part of a balloon to length a of the whole balloon -- when d/a exceeds 0.95, the area of jointing of a balloon becomes small too much, and there is a possibility that adhesive strength may run short. The swelling beforehand given to an inflating part as the ratio of the outer diameter b of the inflating part of a balloon to the outer diameter c of jointing of a balloon is less than 1.03 is small, and adhesives overflow jointing into an inflating part, and there is a possibility that a balloon may carry out eccentricity at the time of expansion. When the ratio of the outer diameter b of the inflating part of a balloon to the outer diameter c of jointing of a balloon exceeded 1.3, and extracting the internal pressure of a balloon and shrinking a balloon, a wrinkle and sag are produced on a balloon and there is a possibility of generating a thrombus. When expanding the balloon of this invention, there is little eccentricity produced on a balloon. The eccentricity of electrode of a balloon can estimate the eccentricity of the balloon which expanded. Drawing 3 is an explanatory view of the eccentricity of electrode of a balloon. Where a balloon is expanded, when it observes from the transverse plane of a balloon catheter, a balloon looks circular even if the balloon which expanded is carrying out eccentricity. When setting the radius from the center O of this circle to a circumference to r and setting distance from the center of this circle to the center of the distal end of a balloon catheter to f, eccentricity of electrode is expressed by f/r. It excels in operativity that it is it easy to deal with a balloon catheter that eccentricity-of-electrode f/r of a balloon is less than 0.1, even if f/r is 0.1-0.2, a balloon catheter can be used for the usual purpose convenient, but when f/r exceeds 0.2, there is a possibility that use top trouble may arise. Since the balloons of this invention are very rare when f/r becomes less than 0.2 and f/r exceeds 0.2, they can usually perform a cardiac output and pressure measuring correctly. Since eccentricity is hardly carried out at the time of expansion, a balloon does not expand too much selectively, and the balloon of this invention is uniformly contracted, when internal pressure is extracted. Therefore, when the internal pressure of a balloon is extracted, where it produced neither a wrinkle nor sag on the balloon and a balloon is shrunk, even if it detains over a long period of time in a blood vessel, there are few possibilities of generating a thrombus.

[0007]Drawing 4 is an explanatory view of one mode of the manufacturing method of the balloon of this invention. As shown in drawing 4 (a), the syringe 10 is equipped with the needle 11 which has an outer diameter equal to the inside diameter of an elastomer tube, the end of the elastomer tube 12 is inserted in a needle, and it fixes with the ring 13 from on the. As a ring, the ring made of hard rubber, the ring made from polytetrafluoroethylene, etc. can be used. It blockades with the pinchcock 14 and other ends of an elastomer tube are fixed. There is no restriction in particular in the method of blockading an elastomer tube and fixing, for example, a cylindrical plug can be inserted in the end of an elastomer tube, and it can fix with a ring from on the. Subsequently, as shown in drawing 4 (b), from a syringe, air is sent in and a tube outer diameter is expanded to 4 or more times. There is a possibility that it may become difficult to form the suitable inflating part for a balloon as the expansion magnification of a tube outer diameter is less than 4 times. Although there is no restriction in particular in the maximum of the expansion magnification of a tube, it is preferred to usually use about [of the elongation of an elastomer] 1/2. If air is extracted in the state where the tube was expanded for several seconds thru/or after holding for several minutes, the inflating part

of a balloon with a larger outer diameter than the original elastomer tube will be formed of the permanent set of an elastomer. The both sides of the inflating part currently fixed serve as the original elastomer tube and jointing of a balloon with an equal outer diameter. It is preferred to select the distance between the fixed ends of a tube suitably beforehand by expansion of a tube, according to the length of the inflating part of the balloon to need, since it is extended also in the length direction while an outer diameter spreads. A portion with equal original elastomer tube of the both ends of the inflating part of the formed balloon and outer diameter is cut to length required as jointing of a balloon, and the balloon of this invention is completed.

[0008]Elongation is not less than 500%, and a permanent set manufactures the balloon of this invention from the tube which consists of an elastomer which is 10 to 20% more preferably 3 to 30%. It is difficult to expand a balloon greatly as elongation is less than 500%, and when it is made to expand greatly by force, there is a possibility that a balloon may be damaged. There is a possibility that it may become difficult to form the inflating part of a balloon which has sufficient outer diameter as a permanent set is less than 3%. When it is made to contract if a permanent set exceeds 30% after expanding a balloon within a blood vessel, there is a possibility of a wrinkle and sag arising on a balloon and generating a thrombus. The permanent set of an elastomer can be measured according to JIS K 6301. In the balloon of this invention, the elastomer of anti-thrombus nature can be used especially conveniently. As such an anti-thrombogenic material, polyurethane, silicone rubber, polyamide, etc. can be mentioned, for example. As polyurethane which has anti-thrombus nature, for example 4 and 4'-diphenylmethane diisocyanate (MDI), 4,4'-dicyclohexyl methanediisocyanate (hydrogenation MDI), hexamethylene diisocyanate, etc. can be used as a polyisocyanate ingredient, and the polyurethane etc. which use polyether polyol, polyester polyol, etc. as a polyol ingredient can be mentioned. The material etc. which blended the peroxide with the methyl silicone rubber which has a vinyl group in a side chain as a cross linking agent as silicone rubber which has anti-thrombus nature, for example can be mentioned. As polyamide which has anti-thrombus nature, the polyamide elastomer etc. which are the block copolymers of Nylon 12 and polytetramethylene glycol can be mentioned, for example. Since the inflating part with a large outer diameter is beforehand formed in the center, a balloon catheter is equipped with the balloon of this invention, and when sending in and swelling a gas, it expands without carrying out eccentricity and can perform correctly measurement of the cardiac output by a thermodilution method, and pressure measuring. Since the balloon of this invention has small eccentricity, it is preferred also as a balloon for balloon catheters used by the biliary system, the urinary system, and a digestive system.

[0009]

[Example]Although an example is given to below and this invention is explained to it still in detail, this invention is not limited at all by these examples.

Example 14, 30.0 g (119.9mmol) of 4'-diphenylmethane diisocyanate (MDI), 104.4g (104.4mmol) of polytetramethylene glycol (PTMG, number average molecular weight 1,000) and the 1.4-butanediol 0.92g (10.2mmol) are mixed, It heated at 80 **, it agitated for 3 minutes, dissolved uniformly, and poured into the metallic mold which carried out the coat of the inner surface by silicone series polymer quickly, and a polyurethane tube the outer diameter of 2.30 mm and 1.90 mm in inside diameter was obtained by heating for 24 hours and fabricating at 100 **. When the marked line of 20 mm of intervals was

described in this polyurethane tube, stress was canceled after maintaining at the state where it elongated so that a marked-line interval might be set to 120 mm, for 10 minutes, and the marked-line interval was measured 10 minutes afterward, it was 23.0 mm, and the permanent set of this polyurethane tube was 15.0%. This polyurethane tube was cut in length of 40 mm, and the needle with an outer diameter of 1.90 ml with which a 10-ml syringe was equipped was stabbed with the end, and the 7-mm-wide ring made of hard rubber was put on the peripheral part, and it fixed to it. The position which is separated from the ring made of hard rubber 6.0 mm was blockaded with the pinchcock. Subsequently, air was sent in from the syringe, and air was extracted after having expanded the tube between the ring made of hard rubber, and a pinchcock so that the outer diameter e might be set to 10.0 mm, and holding it for 5 seconds. The outer diameter of the portion in which the tube was pressed down by the ring made of hard rubber and the pinchcock is 1.90 mm.
The length of the portion into which the outer diameter of the swollen portion swelled 2.65 mm was 6.9 mm.
Respectively it left the portion currently pressed down by the ring made of hard rubber, and the pinchcock every 1.05 mm, it was cut, and the balloon was obtained. length a of 6.9 mm and the whole balloon of length d of the inflating part of this balloon is 9.0 mm -- a ratio -- d/a is 0.77 and the outer diameter c of jointing of 2.65 mm and a balloon of the outer diameter b of the inflating part of a balloon is 2.30 mm -- a ratio -- b/c is 1.15. The balloon made from this polyurethane was inserted in the balloon applied part of the catheter tube made from polyurethane, and was pasted up on the catheter tube using cyanoacrylate adhesive in jointing of a balloon, and 13 balloon catheters were produced. About these ten balloon catheters, 1.7 ml of air was poured in using the syringe, the balloon was expanded, and eccentricity was evaluated. That in which eccentricity of electrode exceeds 0.2 by one did not have [the thing of 9 and eccentricity of electrode 0.1-0.2] a with an eccentricity of electrode of less than 0.1 thing among ten balloon catheters. The introducer sheath was used for the subclavian vein of the goat of three females, these three balloon catheters were inserted in it, respectively, 1.7 ml of air was poured in, the balloon was blown up, and it passed to the pulmonary artery tee, and air was extracted, the balloon was shrunk, and it detained for three days. The balloon catheter was pulled out after that and the state of the balloon was observed. Neither a wrinkle nor sag is in any balloon, and generation of a thrombus was not accepted.
except the interval of the ring made of example 2 hard rubber and a pinchcock having been 3.6 mm, the same operation as Example 1 is repeated and length d of the inflating part of a balloon is [length a of 4.1 mm and the whole balloon] 9.0 mm -- a ratio -- d/a is 0.46.
the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.65 mm and a balloon -- 2.30 mm -- a ratio -- b/c obtained the balloon which is 1.15. 13 balloon catheters were produced like Example 1 using the balloon made from this polyurethane. About these ten balloon catheters, eccentricity was evaluated like Example 1. That in which eccentricity of electrode exceeds 0.2 by two did not have [the thing of 8 and eccentricity of electrode 0.1-0.2] a with an eccentricity of electrode of less than 0.1 thing among ten balloon catheters. Anti-thrombus nature was evaluated like Example 1 about these three balloon catheters. Neither **** nor sag is in any balloon, and generation of a thrombus was not accepted.

except the interval of the ring made of example 3 hard rubber and a pinchcock having been 7.0 mm, the same operation as Example 1 is repeated and length d of the inflating part of a balloon is [length a of 8.1 mm and the whole balloon] 9.0 mm -- a ratio -- d/a is 0.90.
the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.65 mm and a balloon -- 2.30 mm -- a ratio -- b/c obtained the balloon which is 1.15.
13 balloon catheters were produced like Example 1 using the balloon made from this polyurethane. About these ten balloon catheters, eccentricity was evaluated like Example 1. That in which eccentricity of electrode exceeds 0.2 by two did not have [the thing of 8 and eccentricity of electrode 0.1-0.2] a with an eccentricity of electrode of less than 0.1 thing among ten balloon catheters. Anti-thrombus nature was evaluated like Example 1 about these three balloon catheters. Neither **** nor sag is in any balloon, and generation of a thrombus was not accepted.
The interval of the ring made of example 4 hard rubber and a pinchcock shall be 6.6 mm, Except having made it expand so that air may be sent in and the outer diameter e may be set to 9.5 mm in the tube between the ring made of hard rubber, and a pinchcock from a syringe, the same operation as Example 1 is repeated and length d of the inflating part of a balloon is [length a of 6.9 mm and the whole balloon] 9.0 mm -- a ratio -- d/a is 0.77.
the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.42 mm and a balloon -- 2.30 mm -- a ratio -- b/c obtained the balloon which is 1.05.
13 balloon catheters were produced like Example 1 using the balloon made from this polyurethane. About these ten balloon catheters, 1.7 ml of air was poured in using the syringe, the balloon was expanded, and eccentricity was evaluated. That in which eccentricity of electrode exceeds 0.2 by three did not have [the thing of 7 and eccentricity of electrode 0.1-0.2] a with an eccentricity of electrode of less than 0.1 thing among ten balloon catheters. Anti-thrombus nature was evaluated like Example 1 about these three balloon catheters. Neither a wrinkle nor sag is in any balloon, and generation of a thrombus was not accepted.
The interval of the ring made of example 5 hard rubber and a pinchcock shall be 5.4 mm, Except having made it expand so that air may be sent in and the outer diameter e may be set to 11.0 mm in the tube between the ring made of hard rubber, and a pinchcock from a syringe, the same operation as Example 1 is repeated and length d of the inflating part of a balloon is [length a of 6.9 mm and the whole balloon] 9.0 mm -- a ratio -- d/a is 0.77.
the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.92 mm and a balloon -- 2.30 mm -- a ratio -- b/c obtained the balloon which is 1.27.
13 balloon catheters were produced like Example 1 using the balloon made from this polyurethane. About these ten balloon catheters, 1.7 ml of air was poured in using the syringe, the balloon was expanded, and eccentricity was evaluated. That in which eccentricity of electrode exceeds 0.2 by one did not have [the thing of 9 and eccentricity of electrode 0.1-0.2] a with an eccentricity of electrode of less than 0.1 thing among ten balloon catheters. Anti-thrombus nature was evaluated like Example 1 about these three balloon catheters. Neither a wrinkle nor sag is in any balloon, and generation of a thrombus was not accepted. The result of Examples 1-5 is shown in the 1st table.
[0010]
[Table 1]

第１表

		実施例１	実施例２	実施例３	実施例４	実施例５
バルーン材質		PU	PU	PU	PU	PU
a（mm）		9.0	9.0	9.0	9.0	9.0
b（mm）		2.65	2.65	2.65	2.42	2.92
c（mm）		2.30	2.30	2.30	2.30	2.30
d（mm）		6.9	4.1	8.1	6.9	6.9
e（mm）		10.0	10.0	10.0	9.5	11.0
d／a		0.77	0.46	0.90	0.77	0.77
b／c		1.15	1.15	1.15	1.05	1.27
e／c		4.3	4.3	4.3	4.1	4.8
偏心率	＜0.1	9	8	8	7	9
（個）	0.1～0.2	1	2	2	3	1
	＞0.2	0	0	0	0	0
血栓の生成		0／3	0／3	0／3	0／3	0／3

[注] PU：ポリウレタン。

[0011]the ratio of length d of the inflating part of a balloon to length a of the whole balloon -- d/a being 0.46-0.90 and, and the ratio of the outer diameter b of the inflating part of a balloon to the outer diameter c of jointing of a balloon -- most of each balloon catheter of Examples 1-5 whose b/c is 1.05-1.27 is less than 0.1 eccentricity of electrode. That in which eccentricity of electrode exceeds 0.2 did not have one piece, either.
Even if detained in the pulmonary artery tee of the female goat for three days, what generated a thrombus did not have one piece, either.
Except the interval of the ring made of comparative example 1 hard rubber and a pinchcock having been 7.5 mm, the same operation as Example 1 is repeated, length d of the inflating part of a balloon is [the length a of 8.8 mm and the whole balloon] 9.0 mm, and the ratios d/a are 0.98.
the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.65 mm and a balloon -- 2.30 mm -- a ratio -- b/c obtained the balloon which is 1.15.
Although the balloon made from this polyurethane was pasted up on the balloon applied part of the catheter tube made from polyurethane using cyanoacrylate adhesive, adhesive strength with it could not be obtained, and evaluation of eccentricity of electrode and anti-thrombus nature was not able to be performed. [a small area of jointing of a balloon and] [sufficient]
except the interval of the ring made of comparative example 2 hard rubber and a pinchcock having been 3.0 mm, the same operation as Example 1 is repeated and length d of the inflating part of a balloon is [length a of 3.4 mm and the whole balloon] 9.0 mm -- a ratio -- d/a is 0.38.
the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.65 mm and a balloon -- 2.30 mm -- a ratio -- b/c obtained the balloon which is 1.15.
13 balloon catheters were produced like Example 1 using the balloon made from this polyurethane. About these ten balloon catheters, 1.7 ml of air was poured in using the

syringe, the balloon was expanded, and eccentricity was evaluated. The number of those in which 2 and eccentricity of electrode exceed [a with an eccentricity of electrode of less than 0.1 thing] 0.2 among ten balloon catheters in the thing of 7 and eccentricity of electrode 0.1-0.2 was one. Anti-thrombus nature was evaluated like Example 1 about these three balloon catheters. Generation of a thrombus was observed in one among three balloons.

The polyurethane tube obtained in comparative example 3 Example 1 is cut in length of 9.0 mm, Insert in the balloon applied part of a catheter tube, paste up each 1.05 mm of the both ends using cyanoacrylate adhesive, and, in length d of the inflating part of a balloon, length a of 6.9 mm and the whole balloon at 9.0 mm. a ratio -- d/a is 0.77 -- the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.30 mm and a balloon -- 2.30 mm -- a ratio -- b/c produced 13 balloon catheters which have a balloon which is 1.00. About these ten balloon catheters, 1.7 ml of air was poured in using the syringe, the balloon was expanded, and eccentricity was evaluated. The number of those in which 2 and eccentricity of electrode exceed [a with an eccentricity of electrode of less than 0.1 thing] 0.2 among ten balloon catheters in the thing of 6 and eccentricity of electrode 0.1-0.2 was two. Anti-thrombus nature was evaluated like Example 1 about these three balloon catheters. Generation of a thrombus was observed in one among three balloons.

The interval of the ring made of comparative example 4 hard rubber and a pinchcock shall be 5.1 mm, Except having made it expand so that air may be sent in and an outer diameter may be set to 13.0 mm in the tube between the ring made of hard rubber, and a pinchcock from a syringe, the same operation as Example 1 is repeated and length d of the inflating part of a balloon is [length a of 6.9 mm and the whole balloon] 9.0 mm -- a ratio -- d/a is 0.77.

the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 3.10 mm and a balloon -- 2.30 mm -- a ratio -- b/c obtained the balloon which is 1.35. 13 balloon catheters were produced like Example 1 using the balloon made from this polyurethane. About these ten balloon catheters, 1.7 ml of air was poured in using the syringe, the balloon was expanded, and eccentricity was evaluated. The number of those in which 2 and eccentricity of electrode exceed [a with an eccentricity of electrode of less than 0.1 thing] 0.2 among ten balloon catheters in the thing of 7 and eccentricity of electrode 0.1-0.2 was one. Anti-thrombus nature was evaluated like Example 1 about these three balloon catheters. Any balloon has **** and sag and three generation of a thrombus was accepted.

The with 1.90 comparative example 5 mm in inside diameter and an outer diameter of 2.30 mm tube made of crude rubber is cut in length of 9.0 mm, Insert in the balloon applied part of a catheter tube, paste up each 1.05 mm of the both ends using cyanoacrylate adhesive, and, in length d of the inflating part of a balloon, length a of 6.9 mm and the whole balloon at 9.0 mm. a ratio -- d/a is 0.77 -- the outer diameter b of the inflating part of a balloon -- the outer diameter c of jointing of 2.30 mm and a balloon -- 2.30 mm -- a ratio -- b/c produced 13 balloon catheters which have a balloon which is 1.00. About these ten balloon catheters, 1.7 ml of air was poured in using the syringe, the balloon was expanded, and eccentricity was evaluated. The number of those in which 2 and eccentricity of electrode exceed [a with an eccentricity of electrode of less than 0.1 thing] 0.2 among ten balloon catheters in the thing of 6 and eccentricity of electrode 0.1-

0.2 was two. When anti-thrombus nature was evaluated like Example 1 about these three balloon catheters, there were not a wrinkle and sag in a balloon, but generation of a thrombus was observed in all three balloons. The result of the comparative examples 1-5 is shown in the 2nd table.

[0012]

[Table 2]

[0013]The balloon of the comparative example 1 which is too large had the low adhesive strength to the balloon applied part of a catheter tube, and evaluation of eccentricity of electrode and anti-thrombus nature of it was not completed. There are some in which eccentricity of electrode exceeds 0.2 in the balloon of the comparative example 2 which is too small, and generation of a thrombus was also accepted. The balloon of the comparative example 3 with an equal outer diameter of the inflating part of a balloon and jointing of a balloon also has some in which eccentricity of electrode exceeds 0.2, and generation of a thrombus was also accepted. The balloon of the comparative example 4 which is too large has some in which eccentricity of electrode exceeds 0.2, and a wrinkle and sag arose on the balloon, and generation of a thrombus was accepted. The balloon made of the crude rubber of the comparative example 3 with an equal outer diameter of the inflating part of a balloon and jointing of a balloon has some in which eccentricity of electrode exceeds 0.2, and generation of a thrombus was observed in all.

[0014]

[Effect of the Invention]Since it can perform measurement of a cardiac output or ** correctly since the balloon of this invention expands without carrying out eccentricity greatly, and it produces neither a wrinkle nor sag at the time of contraction, there are few possibilities that a thrombus may generate.

CLAIMS

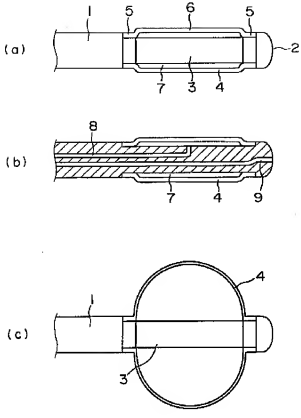
[Claim(s)]
[Claim 1]it is a balloon with which a distal end of a balloon catheter is equipped -- a ratio of length d of an inflating part of a balloon to length a of the whole balloon -- d/a being 0.4-0.95 and, and a ratio of the outer diameter b of an inflating part of a balloon to the outer diameter c of jointing of a balloon -- a balloon for balloon catheters, wherein b/c is 1.03-1.3.
[Claim 2]Press down a both-ends portion used as jointing of a balloon of a tube which consists of an elastomer whose elongation is not less than 500%, and whose permanent set is 3 to 30% from a peripheral part, and it fixes, A manufacturing method of a balloon for the balloon catheters according to claim 1 fabricating by blockading one end of a tube, pouring in a gas or a fluid from the other end, and expanding an outer diameter of a tube to 4 or more times.

DESCRIPTION OF DRAWINGS

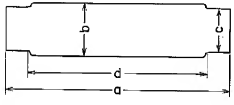
[Brief Description of the Drawings]
[Drawing 1]Drawing 1 is the side view and sectional view equipped with the balloon of this invention of a distal end of a balloon catheter. [of one mode]
[Drawing 2]Drawing 2 is a size explanatory view of the balloon of this invention.
[Drawing 3]Drawing 3 is an explanatory view of the eccentricity of electrode of a balloon.
[Drawing 4]Drawing 4 is an explanatory view of one mode of the manufacturing method of the balloon of this invention.
[Drawing 5]Drawing 5 is a side view of the distal end of the conventional balloon catheter.
[Description of Notations]
1 Catheter tube
2 Distal end
3 Balloon applied part
4 Balloon
5 Jointing
6 Inflating part
7 Opening
8 The lumen for gases
9 The lumen for pressure surveies
10 Syringe
11 Needle
12 Elastomer tube
13 Ring
14 Pinchcock

DRAWINGS

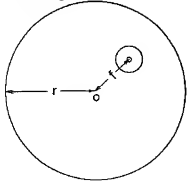
[Drawing 1]



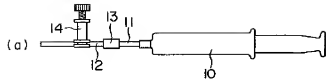
[Drawing 2]

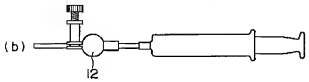


[Drawing 3]



[Drawing 4]





[Drawing 5]